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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,290	10/15/2003	Ivan Osorio	011738.00134	8970
22908	7590	02/27/2006	EXAMINER	
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			ROBERTS, DARIN	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,290

Applicant(s)

OSORIO ET AL.

Examiner

Darin R. Roberts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-21, 23-27, 30, 31, 33-36 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 12, 22, 28, 29, 32, 37 and 38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/23/04</u> . | 6) <input checked="" type="checkbox"/> Other: <u>4/26/04</u> . |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In reference to claims 15-18, the aforementioned claims are both vague and indefinite because it is unclear as to whether the applicant has positively recited a pulse generator or a drug delivery system. The applicant should set forth a pulse generator or drug delivery device first before specifying its use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5, 6, 8, 10, 13-19, 23-27, 30, 33- 36, 39, & 42 are rejected under 35 U.S.C. 102(e) as being anticipate by Whitehurst (US 6782292 B2).

In reference to **claims 1, 10 14, 16, 23 & 24, 33, & 42**, the Whitehurst patent teaches an implantable device, which is inherently medical in nature, that is capable of providing treatment therapy to treat nervous system disorder comprising of an implantable monitoring device referred to as a sensor used for the purpose of sensing a neurological condition and generation a neurological signal (see abstract & column 5, lead lines 40-42). The Whitehurst patent also teaches therapy delivery element coupled to a monitoring element referred to as a sensor wherein the therapy device is capable of delivering therapy to the therapy delivery element and receiving the neurological signal from the monitoring element (see abstract & lines 24-42). The Whitehurst patent also teaches the activation of therapy via a closed loop system (see abstract) and due to the fact that the Whitehurst system is a closed loop system the occurrence of undesired administering of therapy is hindered (see abstract & column 7, lead lines 1-7). The Whitehurst patent also teaches the use of a processor used for activating the therapy device to begin operation, preventing the therapy device from delivering therapy to the patient for a predetermined time period after the therapy device has been activated (see column 11, lead lines 40-47 & column 12, lead lines 28-35).

In reference to **claim 2**, the Whitehurst patent teaches a therapy device that is at least a signal generator (see column 5, lead lines 26-27), and wherein the therapy delivery element and the monitoring element are at least one electrode (see column 5, lead lines 26-27 & lead lines 40-42).

In reference to **claim 3**, the Whitehurst patent teaches providing treatment therapy wherein the therapy device is at least a drug delivery device, the therapy

delivery element is a catheter, and the monitoring element is at least one sensor (see abstract & column 5, lead lines 28-31).

In reference to **claim 5**, the Whitehurst device teaches the treatment of mental health disorder and psychiatric disorder (see column 4, lead lines 64-66).

In reference to **claims 6 & 13**, the Whitehurst patent teaches a method of providing treatment therapy wherein the step of implanting at least one monitoring element comprises the step of implanting a sensor in the brain of the patient for monitoring EEG activity (see column 14, lead lines 15-19, & lead lines 26-30).

In reference to **claim 8**, the Whitehurst patent teaches providing treatment therapy wherein the step of activating comprises the step of monitoring a neurological condition of the patient (see column 14, lines 2-10).

In reference to **claim 14**, the Whitehurst patent teaches an implantable device that is capable of providing treatment therapy to treat nervous system disorder comprising of an implantable monitoring device referred to as a sensor used for the purpose of sensing a neurological condition and generation a neurological signal (see abstract & column 5, lead lines 40-42). The Whitehurst patent also teaches therapy delivery element coupled to a monitoring element referred to as a sensor where in the therapy device is capable of delivering therapy to the therapy delivery element and receiving the neurological signal from the monitoring element (see abstract & lines 24-42). As well as activation of therapy via a closed loop system and due to the fact that the system is a closed loop system the occurrence of undesired administering of therapy is hindered. The Whitehurst patent also teaches the use of a processor used for

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activating the therapy device to begin operation, preventing the therapy device from delivering therapy to the patient for a predetermined time period after the therapy device has been activated (see column 11, lead lines 40-47 & column 12, lead lines 28-35).

In reference to **claim 15**, the average pulse generator inherently possesses a pulse generator.

In reference to **claims 17, & 18**, the Whitehurst patent teaches the controller of the device can be external (see column 6, lead lines 36-42).

In reference to **claim 19**, the Whitehurst patent teaches a means for sensing the disorder or symptoms thereof, or other measures of the state of the patient such symptoms can include electrical activity within the brain of the patient (see column 6, lead lines 65-67).

In reference to **claim 27 & 30, 36, 39**, the Whitehurst patent teaches controlling treatment therapy wherein at least one of the therapy parameters is charge density and the step of determining comprises the step of determining whether the programming information will result in the therapy delivering a charge density above a predetermined charge density limit. The Whitehurst patent teaches applying current (which is a measure of charge density) to the desired brain tissue, and because the device is a closed loop system it is inherently capable of determining whether the therapy is beyond the desired limit (see abstract & column 7, lead lines 1-7).

In reference to **claim 25, 26, 34, & 35**, the Whitehurst patent teaches that an SCU may communicate with a remote control that is capable of sending commands and/or data to an SCU and that is preferably capable of receiving commands and/or

data from an SCU. The Whitehurst patent also teaches that an SCU of the present invention may be activated and deactivated, programmed and tested through a programmer, a clinician programming system, or a manufacturing and diagnostic system (see column 13, lead lines 9-16). Whitehurst also teaches the use of a first implanted SCU associated with sensing that is capable programming a second implanted SCU associated with stimulation (see column 14, lead lines 26-31). The sensing SCU can be associated with "neurotransmitter levels and/or their associated breakdown product levels" thus preventing the occurrence of treatment outside of the necessary range by using the sensed information to preferably control the stimulation parameters of the SCU(s) in a closed-loop manner (see column 14, lead lines 26-34).

Claims 1, 4, 7, 9, 14, 20, 31, 34, 40, 41 &, is rejected under 35 U.S.C. 102(e) as being anticipated by Greene (US 6529774 B1).

In reference to **claims 1, 14, & 34**, the Greene patent teaches a method for providing treatment therapy by a medical device to treat a nervous system disorder (see abstract) comprising the steps of implanting at least one therapy delivery element within a body of a patient, implanting at least one monitoring element for sensing a neurological condition and generating a neurological signal (see abstract & column 4, lines 56-60). Greene also teaches coupling the therapy delivery element and the monitoring element to a therapy device, wherein the therapy device is capable of delivering therapy to the therapy delivery element and receiving the neurological signal from the monitoring element, activating the therapy device to begin operation (see

column 4, lead lines 54- 67), and preventing the therapy device from delivering therapy to the patient for a predetermined time period after the therapy device has been activated (column 7, lead lines 59-67). The Greene patent also teaches that the “variation of the parameters may be based either upon a preprogrammed sequence or based upon some characteristic of the detected epileptiform activity. Application of the responsive or somatosensory stimulation may be temporally paused or the amplifier blanked during that stimulation to allow analysis of the electrical activity of the brain and thence determine whether the stimulation has had its desired effect. Readjustment of the parameters of the stimulation may be repeated as long as it is advantageous in terminating the undesirable epileptiform activity” (see column 6, lead lines 48-57)

In reference to **claim 4, 7, 9, & 20**, the Greene patent teaches a method of providing treatment therapy wherein Greene uses the brain’s electrical activity to determine the onset of a seizure (see abstract & column 4, lead lines 54- 67)

In reference to **claim 31 & 40**, the Greene device teaches “less than a second and up to 15 minutes or more” (see column 7, lead lines 30-31).

In reference to **claim 41**, because the Greene device is capable of stimulating for time periods “less than a second and up to 15 minutes or more” (see column 7, lines 30-31), the Green device inherently has an ON time between one second and 24 hours.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 21, are rejected under 35 U.S.C. 103(a) as being obvious over Greene (US 6529774 B1).

In reference to **claim 11 & 21**, the Greene patent discloses the claimed invention but does not disclose expressly the 30-minute time frame. It would have been an obvious matter of choice to a person of ordinary skill in the art to modify the neurostimulation device as taught by Greene with a time frame in which the device can acquire data after implantation, because the applicant has not disclosed that the 30-minute time frame provides an advantage, is used for a particular purpose, or solves a stated problem by stating that "the time period is a function of the background window length and may vary in duration" (see pp. [137] of applicant's disclosure). One of ordinary skill in the art furthermore would have expected applicant's invention to perform

equally as well in conjunction with the Greene neurostimulator because it provides a timeframe in which the Greene device can acquire data after implantation to allow for the determination of proper stimulation parameters and since it appears to be an arbitrary design consideration which fails to patentably distinguish over the Greene patent.

Therefore it would have been obvious matter of design choice to modify the Greene device to obtain the invention specified in the aforementioned claims.

Allowable Subject Matter

Claims 12, 22, 28, 29, 32, 37, & 38 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The examiner wishes to site patents by Boveja (US 6356788 B2), Lozano et al. (US 6356784 B1), and Barreras, Sr, et al. (US 5735887 A) Due to the fact that they mention the use of an implantable device used for the treatment of nervous system disorders including seizures as well as the use of external and internal parts.

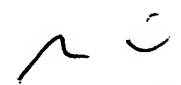
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darin R. Roberts whose telephone number is (571)272-5558. The examiner can normally be reached on 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Darin Roberts
Patent Examiner
Art Unit 3762

D. R.


GEORGE R. EVANISKO
PRIMARY EXAMINER
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